Supreme Court, U.S.
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No. 99-

IN THE

Supreme Court of the United States

ABBOTT LABORATORIES,

Petitioner,

v.

GENEVA PHARMACEUTICALS, INC.,
NOVOPHARM LTD. and INVAMED, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Under § 102(b) of the Patent Act of 1952, a United States patent may be invalidated if the patented invention was put "on sale in this country, more than one year prior to the date of application for a patent. . . ." In this case, the Court of Appeals for the first time held a patent invalid based upon a third party's prior, *unknowing* manufacture and sale of a new chemical compound. The questions presented for review by this Court are:

(1) Can a patent for a new chemical compound be invalidated under § 102(b) of the Patent Act because of a third party's prior manufacture and sale of that compound, if the manufacturer of the compound and all other parties involved in the sale were unaware of the existence of the new compound?

(2) Is the Federal Circuit's holding that proof of an inventor's conception is irrelevant to the § 102(b) inquiry in conflict with this Court's holding in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304, 308 (1998), that "[t]he primary meaning of the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea"?

PARTIES TO THE PROCEEDING

The petitioner, Abbott Laboratories, was the plaintiff-appellant below. The respondents, Geneva Pharmaceuticals, Inc., Novopharm Ltd. and Invamed, Inc., were the defendants-appellees below. There are no other parties to this litigation. Related cases pending in the Court of Appeals for the Federal Circuit involve Mylan Pharmaceuticals, Inc. (Case No. 99-1325) and Warner Chilcott, Inc. (Case No. 99-1096).

Petitioner, Abbott Laboratories, has no parent corporation and no publicly held company owns 10% or more of its stock.

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The opinion of the United States Court of Appeals for the Federal Circuit is reported at 182 F.3d 1315 (Fed. Cir. 1999) and appears in Appendix A. The district court's unreported order granting summary judgment appears in Appendix B.

STATEMENT OF JURISDICTION

The opinion and order of the Court of Appeals for the Federal Circuit was entered on July 1, 1999 (Appendix A). The Court of Appeals denied a timely petition for rehearing and suggestion for rehearing *en banc* on August 5, 1999 (Appendix C).

The Federal Circuit's jurisdiction was based upon 28 U.S.C. § 1295(a)(1). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 102 of the Patent Act, codified at 35 U.S.C. § 102, provides in relevant part:

> A person shall be entitled to a patent unless —
>
> * * *
>
> (b) the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . .

STATEMENT OF THE CASE

After scientists working at Abbott Laboratories (hereinafter "Abbott") discovered terazosin hydrochloride, a chemical compound useful for treating high blood pressure and enlargement of the prostate, Abbott was awarded a United States Patent covering that compound. Abbott scientists subsequently discovered that terazosin hydrochloride exists in different crystal forms, or polymorphs. Different polymorphs of a compound may vary in characteristics such as density, hardness or solubility, and they have been found to be unique and patentable inventions. *See Zenith Laboratories v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1419-20 (Fed. Cir.), *cert. denied*, 513 U.S. 995 (1994).

In the early 1990s, Abbott discovered a previously unknown polymorph of terazosin hydrochloride known as "Form IV." Abbott received United States Patent 5,504,207 ("the '207 patent") covering the Form IV polymorph on April 2, 1996. Abbott subsequently brought suit against the defendants-respondents, each of which had announced its intention to market a pharmaceutical product containing Form IV terazosin hydrochloride.

The defendants moved for summary judgment on the ground that 35 U.S.C. § 102(b), also known as the "on-sale bar," rendered Abbott's '207 patent invalid. The defendants relied upon three sales of Form IV that had occurred between 1990 and 1992, more than one year before Abbott filed the application that resulted in the '207 patent.[1]

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1. Abbott did not participate in any of the three transactions in question, each of which involved the sale of terazosin hydrochloride that had been manufactured by a foreign manufacturer and sold to an unrelated third party.

In response to the defendants' summary judgment motions, Abbott pointed to the absence of evidence that any of the buyers, sellers, or manufacturers of the chemical compound that was sold was aware that the compound contained the Form IV polymorph. The evidence in the record instead suggested that the parties believed that their transactions involved crystalline forms of terazosin hydrochloride that were already known to exist. Abbott argued that a summary judgment of invalidity was inappropriate in light of that evidence, particularly since the defendants bore the burden of proving invalidity by clear and convincing evidence. *See generally* 11 James Moore, *Moore's Federal Practice* § 56.03[4] (3d ed. 1998) ("If the claimant seeking summary judgment also must satisfy the clear and convincing standard at trial, summary judgment is nearly always unattainable.").

The District Court nevertheless granted summary judgment, holding that it was "immaterial" that the parties involved in the transactions were unaware of the existence of Form IV terazosin hydrochloride. Appendix B at 25a. The District Court apparently believed that all that mattered under section 102(b) was whether the compound had been *physically* manufactured and sold, not whether anyone had known at the time that the Form IV polymorph existed. *Id.*

While Abbott's appeal from the District Court's judgment was pending in the Court of Appeals for the Federal Circuit, this Court decided *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998). In *Pfaff*, this Court was faced with the issue of whether the on-sale bar would be applied when the invention that was the subject of a prior sale had not been manufactured or otherwise "reduced to practice" at the time of the sale. The Court, in a unanimous

opinion by Justice Stevens, began its analysis by stating that "[t]he primary meaning of the word 'invention' in the Patent Act *unquestionably* refers to the inventor's *conception* rather than to a physical embodiment of that idea." *Pfaff*, 119 S. Ct. at 308 (emphasis added). The Court also held that as used in section 102(b) of the Patent Act, "[t]he word 'invention' must refer to a *concept that is complete*, rather than merely 'substantially complete.' " *Id.* at 311 (emphasis added).

The Court concluded in *Pfaff* that a reduction to practice was not an essential element for application of the on-sale bar and that the patent at issue in that case was invalid under § 102(b). The Court applied a two-part test for the application of § 102(b). *See Pfaff*, 119 S. Ct. at 311 ("First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting."). The Court's determination that the on-sale bar applied was based in large part upon the inventor's concession that he had conceived of the patented device prior to the time he accepted orders for it. *Id.* at 311-12 (noting that because the process of conception was complete, the inventor was able to "understand and control" the timing of the device's first commercial sale).

Abbott argued to the Court of Appeals that under *Pfaff*, a finding that conception had occurred was a fundamental prerequisite to an on-sale bar determination. Abbott contended that because section 102(b) of the Patent Act explicitly requires proof that an "invention" has been put on sale, and because *Pfaff* holds that "the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea," *Pfaff*, 119 S. Ct. at 308, it necessarily follows that an *unknowing* manufacture and sale of a previously unknown

chemical compound cannot trigger the on-sale bar.[2] Abbott argued that in the absence of evidence that the third party manufacturers or their customers had recognized the existence of the Form IV polymorph or had appreciated its novelty, the entry of summary judgment based on the on-sale bar was inappropriate.

The Court of Appeals disagreed, holding that "[t]he sale of the material in question obviates any need for inquiry into conception." Appendix A at 7a. Applying this strict "embodiment" test, the Court concluded that "[t]he fact that the parties to the sales transactions did not know they were dealing in Form IV at the time of the sales is therefore irrelevant to the question whether it was 'on sale' before the critical date." *Id.* at 8a.

Based upon its conclusion that conception is irrelevant under section 102(b) and that neither the third party manufacturers nor any other party need have known of the existence of Form IV terazosin hydrochloride for the on-sale bar to apply, the Court of Appeals affirmed the District Court's judgment of invalidity. *Id.* at 9a. Abbott's petition for rehearing and suggestion for rehearing *en banc* were subsequently denied (Appendix C). This petition followed.

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2. The Patent and Trademark Office, which was aware of two of the three transactions in question prior to its issuance of the '207 patent to Abbott, had concluded that the parties' lack of awareness was dispositive. As the patent examiner explained, "[t]he two transactions from Byron Chemical Co. to Geneva . . . are not 'on sale' bar of the Form IV of claim 4 because neither Byron nor Geneva at the time of the transactions knew that Form IV was involved." Appendix B at 24a.

REASONS FOR GRANTING THE WRIT

I.

THE COURT OF APPEALS' HOLDING THAT CONCEPTION IS IRRELEVANT TO THE "ON SALE BAR" ANALYSIS IS IN DIRECT CONFLICT WITH THIS COURT'S DECISION IN *PFAFF v. WELLS ELECTRONICS.*

A patent "shall be presumed valid," 35 U.S.C. § 282, and a party challenging the validity of a patent bears the burden of establishing invalidity by clear and convincing evidence. *See Seal-Flex, Inc. v. Athletic Track and Court Const.*, 998 F.3d 1318, 1324 (Fed. Cir. 1996). Under the Patent Act, one method of establishing invalidity is to show by the requisite clear and convincing evidence that "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States. . . ." 35 U.S.C. § 102(b). Although most section 102(b) cases involve the sale of an invention by the patent applicant itself or a related party, the courts have held that sales by unrelated parties can also trigger the on-sale bar. *See, e.g., Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1580 n.14 (Fed. Cir. 1984). Abbott knows of no reported decision, however, where a court has invalidated a patent based upon a third party's prior, *unknowing* manufacture and sale of a new chemical composition.

Under the Federal Circuit's unprecedented holding in this case, the first party to conceive of a new and useful chemical compound can be deprived of its ordinary, Constitutionally-secured reward for adding to this nation's "store of knowledge" because of a foreign manufacturer's

unknowing manufacture and sale of that compound a few years prior to the true inventor's accomplishment. For the reasons set out below, neither *Pfaff* nor the Patent Act permits that result. While there is no split among the Circuits on this issue — because the Federal Circuit hears all patent appeals — the far reaching and detrimental consequences of the Court of Appeals' approach are self-evident, and this case thus fully warrants this Court's attention.

As this Court held last Term in *Pfaff*, the word "invention" as used in § 102(b) of the Patent Act means the inventor's "conception" of its new process, device or composition of matter. *Pfaff*, 119 S. Ct. at 308, 311. *Pfaff* involved a patent for a computer chip socket. The inventor in *Pfaff* had prepared "detailed engineering drawings that had described the design, the dimensions, and the materials to be used in making" the new socket. *Id.* at 307. He had then shown a sketch of his concept to a prospective buyer, which had subsequently placed an order for the new sockets. *Id.* Because all of this activity had occurred more than one year before the inventor applied for a patent covering the socket, this Court held that the inventor had "lost his right to patent his invention." *Id.*

Although the inventor in *Pfaff* had obviously *conceived of* his new socket — and offered to sell it — more than one year before he applied for a patent, he argued that his invention had not been placed "on sale" under § 102(b) because it had not yet been *manufactured* according to his drawings and specifications. *Id.* at 310. In rejecting this argument, this Court relied primarily upon the text of the Patent Act. § 102(b) of the Act provides that no person is entitled to patent an "invention" that has been "on sale" more than one year before the filing of a patent application. As

Justice Stevens noted for the Court in *Pfaff*, § 100 of the Patent Act defines "invention" as meaning "invention or discovery," and § 101 further provides that "[w]hoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor. . . ." *Id.* at 308 n.8, 309 n.9. In light of these provisions, the Court in *Pfaff* explained that the Patent Act does not require that an "invention" be manufactured or "reduced to practice" before it can be patented. *Id.* at 308-09. Instead, it is "the inventor's *conception*" that is the touchstone for patentability, *not* the "physical embodiment of [its] idea." *Id.* at 308 (emphasis added). *See also Dann v. Johnston*, 425 U.S. 219, 225 (1976) ("As a judicial test, 'invention' — *i.e.*, 'an exercise of the inventive faculty,' has long been regarded as an absolute prerequisite to patentability") (citation omitted); *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (holding that patent rights do not attach until an inventor possesses "the complete mental picture of the invention").[3]

The Court in *Pfaff* noted that 35 U.S.C. § 102(b) "serves as a limiting provision" on an inventor's right to a patent, reflecting Congress' effort to strike a balance between "the public's right to retain knowledge already in the public

3. The Patent Act's use of "discovery" as synonymous with "invention" necessarily means that an "inventor" must have a recognition and appreciation of his or her accomplishment. *See* Webster's Third New International Dictionary 647 (1968) (defining "discovery" as "an instance of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized."). As this Court pointed out in *Pfaff*, the Patent Act's focus on "discovery" also underlies the rule that the first person to conceive a new and useful composition of matter is ordinarily entitled to a patent, even if he is not the first to reduce it to practice. *Pfaff*, 119 S. Ct. at 309.

domain and the inventor's right to control whether and when he may patent his invention." *Id.* at 310. Section 102(b) also reflects Congress' "interest in providing inventors with a definite standard for determining when a patent application must be filed." *Id.* at 311. In furtherance of these "basic policies underlying the statutory scheme," and in accordance with the statutory text, the Court held that the word "invention" in section 102(b) "must refer to a concept that is complete . . . ." *Id.* at 311.

When applied to section 102(b), the rule that patent rights do not attach until the inventor possesses a "concept that is complete" means, for example, that the public use or sale of a new device or process will not trigger section 102(b) if the process of experimentation — what this Court in *Dann* called the "exercise of the inventive faculty" — is still ongoing. As the Court noted in *Pfaff*, an inventor who manufactures a new device may "conduct extensive testing without losing his right to obtain a patent for his invention — even if such testing occurs in the public eye." *Id.* Under this "experimental use" doctrine, the process of invention is not complete upon mere manufacture, and section 102(b) is not applicable, unless and until *conception* is also complete. *Id. See also UMC Electronics Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988) (where an inventor "was working towards development of [a] conception, it can be said there is not yet any 'invention' which could be placed on sale.").

The requirement that the process of conception be complete before an on-sale bar can arise is fully consistent with the "basic policies underlying the statutory scheme". *Id.* at 311. Until conception has occurred, there can be no "existing knowledge" or "idea" that has become known to

the public. *Pfaff*, 119 S. Ct. at 310-311. Once the process of conception *is* complete, however, "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention," and section 102(b) should provide him "with a definite standard for determining when a patent application must be filed." *Id.* The Court in *Pfaff* accordingly held that the one-year period set out in § 102(b) begins to run "when an invention that is *ready for patenting* is first marketed commercially." *Id.* at 312 (emphasis added).

In short, *Pfaff* requires that before an on-sale bar can arise under section 102(b), a new device, chemical composition or other invention must be "ready for patenting," *i.e.*, the process of conception "must" be complete. *Id.* at 311-312. As a result, the Court of Appeals' holding in this case that conception was "irrelevant" is a direct repudiation of *Pfaff's* holdings and a fundamental misreading of the text and purposes of the Patent Act.

II.

IN THE ABSENCE OF PROOF OF CONCEPTION, A SUMMARY JUDGMENT OF INVALIDITY WAS IMPROPERLY GRANTED IN THIS CASE.

The District Court did not find, and on the record before it could not have found, that the foreign manufacturers who had manufactured and sold a chemical compound containing the Form IV polymorph of terazosin hydrochloride had appreciated or recognized the existence of Form IV.[4]

4. The District Court accepted the defendants' arguments that conception was irrelevant to their section 102(b) defenses and stated that "[t]he apparent failure of the parties to appreciate that the product had a particular crystal form does not overcome the fact that Form IV terazosin hydrochloride was sold. . . ." Appendix B at (Cont'd)

Conception, invention and patentability were therefore absent, for it has long been the law that a new crystalline form of a chemical compound has not been conceived or reduced to practice, even if it has been manufactured, "where there has been no recognition or appreciation of the existence of the new form." *Silvestri v. Grant*, 496 F.2d 593, 597 (C.C.P.A. 1974). *Silvestri* involved a dispute over who had invented a new crystalline form of ampicillin. The Court of Appeals held that the proper "inventor" of the new form of ampicillin under the Patent Act was the party that had first "recognized and appreciated that a new form of ampicillin had been obtained." *Id.* at 599. The *Silvestri* court explained that:

> [t]he ampicillin [claimed in the patent] is a new form of an otherwise old composition. It is now well settled that in such a case there is no conception or reduction to practice where there has been no recognition or appreciation of the new form.

Id. at 597. *Accord, Heard v. Burton*, 333 F.2d 239, 243-44 (C.C.P.A. 1964) (scientist's failure to recognize that he had created a new crystalline form of an existing chemical compound meant that he had neither conceived nor reduced to practice an "invention" under the Patent Act).

Silvestri and *Heard* thus make it clear that a new crystalline form of an existing chemical compound has not been *conceived*, regardless of its *manufacture*, "absent a contemporaneous recognition that the new form had been obtained. . . ."). *Silvestri*,

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(Cont'd)

26a. The Court of Appeals similarly acknowledged "that the parties to the sales transactions did not know they were dealing in Form IV at the time of the sales. . . ." Appendix A at 8a. *See also id.* at 6a (referencing "the parties' ignorance that they were dealing with Form IV . . . .").

496 F.2d at 597 (noting that despite the earlier manufacture of a new crystalline form by the patent challengers in *Heard*, "until they recognized their accomplishment, the preparation of the new form by each of the appellants remained in the accidental and unappreciated category. *A fortiori*, no right to a patent arose prior to such recognition.").

Silvestri and *Heard* apply the settled principle, recognized in *Pfaff*, *Dann* and numerous other cases, that where conception has not occurred, an "invention" is not "ready for patenting." *Pfaff*, 119 S. Ct. at 311-312. *Pfaff* also holds squarely that an invention *must* be "ready for patenting" before an on-sale bar can arise. *Pfaff*, 119 S. Ct. at 312. If conception is not complete, after all, the inventor cannot "understand and control the timing of the first commercial marketing of the invention." *Id.* at 311. Moreover, if conception has not occurred, and no one has recognized or appreciated that a new and useful composition of matter has been created, there can be no concern over the removal of "existing knowledge" from the public domain. *Id.* at 310.

When *Pfaff* is applied to the facts of this case, it is apparent that the record does not support a summary judgment of invalidity based on an on-sale bar defense. Because the record does not demonstrate that *anyone* was aware of the existence of a new crystalline form of terazosin hydrochloride at the time of the sales in question, Form IV terazosin hydrochloride had not been conceived, and was not "ready for patenting", at that time. *Id.* at 312. *Pfaff* holds squarely that section 102 is inapplicable in that circumstance. *Id.*

The policies underlying the Patent Act also point away from a finding of invalidity here. Because no buyer or seller

knew that it was buying or selling Form IV, there was no new "knowledge" or "idea" that had entered the public domain at the time of the sales in question, and there can be no concern about removing "existing knowledge" from public use. *Id.* at 310. In addition, if a prior, *unknowing* sale of a chemical compound could trigger the running of the one-year period to file a patent application, Congress' "interest in providing inventors with a definite standard for determining when a patent application must be filed" would not be served at all. *Id.* at 311. Instead, an inventor such as Abbott that is unaware of a prior, unknowing manufacture and sale by a third party would have no way of determining when it needed to file its patent application in order to avoid a section 102(b) bar. Indeed, under the Court of Appeals' holding in this case, the one-year period could begin *and end* — as it did here — without *anyone* ever conceiving of the "invention" in question. As a consequence, *no one* would have the ability to "control the timing of the first commercial marketing of [the] invention." *Id.*

The Court of Appeals did purport to apply *Pfaff* in this case. Its application of *Pfaff* represents, however, nothing less than a fundamental repudiation of that case. The Court of Appeals held that all that need be shown for the on-sale bar to arise is that "the claimed material was sold under circumstances in which no question existed that it was useful. . . ." Appendix A at 7a. The Court of Appeals also suggested that Form IV was "ready for patenting" at the time of its manufacture because it had been thereby "reduced to practice." *Id.* at 6a. The Court of Appeals erred. The "material" that was sold here was "useful" because it was known to be *a* crystalline form of terazosin hydrochloride — presumably a form already known to the public. But the "material" was not "ready for patenting" until an inventor

recognized it was *both* "new *and* useful. . . ." 35 U.S.C. § 102 (emphasis added). The record in this case certainly does not contain the requisite clear and convincing evidence that anyone had, prior to Abbott, appreciated the *novelty* of Form IV. Only when that occurred was Form IV "ready for patenting," for mere manufacture alone, without "recognition or appreciation" of the inventive subject matter, does not constitute conception *or* reduction to practice. *Silvestri*, 496 F.2d at 597. *See also Smith v. Hall*, 301 U.S. 216, 232 (1937) (requiring evidence in connection with a "prior use" challenge to a method patent that the alleged prior user both "knew and used" the method); *Tilghman v. Proctor*, 102 U.S. 707, 712 (1880) (holding that the prior manufacture of a fat acid "without exciting attention and without its even being known what was done or how it had been done" did not invalidate a patent covering the subsequent discovery of a process to manufacture the acid).

The Court of Appeals also asserted that section 102(b) does not permit the "withdrawal of inventions that have been placed into the public domain through commercialization." Appendix A at 8a. Again, the Court misapplied *Pfaff*, which states that section 102(b) "exclud[es] *ideas* that are in the public domain from patent protection . . ." and reflects a "reluctance to allow an inventor to remove *existing knowledge* from public use." *Pfaff*, 119 S. Ct. at 310 (emphasis added). There is no probative evidence in the record that any "existing knowledge" of Form IV terazosin hydrochloride or its method of manufacture were in the public domain at *any* time prior to Abbott's patent application. As the Patent and Trademark Office properly recognized, it was Abbott that was therefore entitled under the Constitution to receive a patent. There is no basis in the Patent Act, in the case law, or in the policies underlying section 102(b) for the contrary result reached below.

CONCLUSION

The Federal Circuit's decision in this case repudiates the fundamental holding of *Pfaff* and undermines the goals of the Patent Act. Under the Federal Circuit's unprecedented approach, the "first inventor to conceive" of a new and useful chemical compound can be stripped of his "normal" right to a patent without *any* opportunity to "understand and control the timing of the first commercial marketing of his invention." *Pfaff*, 119 S. Ct. at 309, 311. The Patent Act permits no such result. Abbott therefore requests that this Court summarily reverse the judgment of the Court of Appeals or, in the alternative, that a writ of certiorari issue to review the Court of Appeals' judgment and opinion.

Respectfully submitted,

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APPENDIX

APPENDIX A — DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND DECIDED JULY 1, 1999

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

98-1593, -1594, -1595

ABBOTT LABORATORIES,

Plaintiff-Appellant,

v.

GENEVA PHARMACEUTICALS, INC.,

Defendant-Appellee,

and

NOVOPHARM LIMITED,

Defendant-Appellee,

and

INVAMED, INC.,

Defendant-Appellee.

DECIDED: July 1, 1999

Appendix A

Before PLAGER, LOURIE, and BRYSON, *Circuit Judges*.

LOURIE, *Circuit Judge*.

DECISION

Abbott Laboratories appeals from the summary judgment of the United States District Court for the Northern District of Illinois holding claim 4 of its United States Patent 5,504,207 invalid under the on-sale provision of 35 U.S.C. § 102(b) (1994). *See Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96 C 3331, 96 C 5868, 97 C 7587 (N.D. Ill. Sept. 1, 1998). Because we conclude that the district court properly granted summary judgment of invalidity, we affirm.

BACKGROUND

Terazosin hydrochloride is a pharmaceutical compound used for the treatment of hypertension and benign prostatic hyperplasia. Abbott Laboratories has marketed it exclusively under the trademark Hytrin® since 1987. Abbott's Hytrin® tablets contain the dihydrate crystalline form of terazosin hydrochloride. Terazosin hydrochloride also exists in four anhydrous crystalline forms, and claim 4 of the '207 patent specifically claims the Form IV anhydrate. Claim 4 reads as follows: "4. The anhydrous Form IV crystalline modification of 1-(4-amino-6, 7-dimethoxy-2-quinazolinyl)-4-(2-tetrahydrofuroyl)piperazine hydrochloride characterized by principal peaks in the powder X-ray diffraction pattern at values of . . . ." The particular peaks are not important to the resolution of this case.

Abbott sued Geneva Pharmaceuticals, Inc., Novopharm Limited, and Invamed, Inc. for infringement of the '207 patent after each of them filed an Abbreviated New Drug Application (ANDA) at the United States Food and Drug Administration seeking approval to market a generic version of Hytrin® containing the Form IV anhydrate.[1] The cases were consolidated in the United States District Court for the Northern District of Illinois. The defendants each raised the affirmative defense of patent invalidity under the on-sale bar of 35 U.S.C. § 102(b), asserting that Form IV was anticipated because it was sold in the United States more than one year before the '207 patent's filing date, October 18, 1994.

It is undisputed on appeal that a company not party to this law suit, Byron Chemical Company, Inc., made at least three sales of Form IV terazosin hydrochloride anhydrate in the United States more than one year before the October 18, 1994 filing date. Byron sold a five-kilogram lot of anhydrous terazosin hydrochloride during the 1989-90 period and another lot in 1991 to defendant Geneva. Byron sold a third lot to Warner Chilcott Laboratories in 1992. Byron did not manufacture the compound itself; it bought it from two foreign manufacturers — Imhausen-Chemie GMBH in Germany and Yogodawa Pharmaceutical Company in Japan. None of these sales transactions specified which crystalline form of the anhydrous compound was being sold. Thus, at the time of the sales, the parties to the United States

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1. It is an act of patent infringement under certain circumstances to file an ANDA seeking approval to commercially manufacture, use, or sell a drug claimed in a patent before the expiration date of such patent. *See* 35 U.S.C. § 271(e)(2)(A) (1994). It is undisputed that such circumstances apply here.

transactions did not know the identity of the particular crystalline form with which they were dealing. It was not until after the United States sales transactions were completed that Abbott and Geneva each tested samples from these lots and determined that the Form IV anhydrate crystal was what had been sold.[2]

On defendants' motions for summary judgment,[3] the district court held that the United States sales invalidated claim 4 under the on-sale bar. The court reasoned that Form IV was in the public domain, that buyers had come to rely on it being freely available, and that it was immaterial that the parties were unaware of the nature of that particular crystal form.

Abbott timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

Summary judgment is proper when there is no genuine issue of material fact and the moving party is entitled to a judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). We review a

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2. Abbott in 1995, and Geneva in 1996, each performed x-ray diffraction analyses on samples from these lots and found that the samples exhibited the pattern of principal peaks at the particular values disclosed in claim 4 that characterize the Form IV anhydrate crystal.

3. Defendants Geneva and Novopharm each filed a motion for summary judgment that claim 4 was invalid under the on-sale bar and joined each other's motions. Defendant Invamed joined both motions.

district court's grant of summary judgment *de novo*. *See Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994). The ultimate determination whether an invention was on sale within the meaning of § 102(b) is a question of law which we review *de novo*. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990).

A patent is invalid under § 102(b) if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States. . . ." Because Abbott filed the application for the '207 patent on October 18, 1994, the critical date for purposes of the on-sale bar is October 18, 1993. As the parties challenging the validity of a presumptively valid patent, *see* 35 U.S.C. § 282 (1994), the defendants bore the burden of proving the existence of an on-sale bar by clear and convincing evidence. In this case, there are no facts in dispute, leaving only the legal issue whether the § 102(b) on-sale bar invalidates the patent. *See UMC Electronics Co. v. United States*, 816 F.2d 647, 657, 2 USPQ2d 1465, 1472 (Fed. Cir. 1987).

Abbott argues that claim 4 is not invalid under the on-sale bar because the "invention" was not on sale. For an "invention" to be on sale, Abbott submits, the parties must "conceive," or *know* precisely, the nature of the subject matter with which they are dealing. Since the parties did not know that they were dealing with Form IV, Abbott reasons, they did not "conceive" the subject matter sold and therefore there was no "invention" on sale. The defendants respond that we need only apply the two-part test for the on-sale bar recently set forth by the Supreme Court in *Pfaff v. Wells*

Electronics, Inc.,[4] and that, under this test, it is irrelevant that the parties to the sales did not know that they were dealing with Form IV rather than with another anhydrous terazosin hydrochloride crystalline form.

We agree with defendants that claim 4 is invalid and that the parties' ignorance that they were dealing with Form IV is irrelevant. The Supreme Court has recently stated a two-part test for determining when the on-sale bar applies. Before the critical date, the invention must both be the subject of a commercial sale or offer for sale and be "ready for patenting." *See Pfaff*, __ U.S. at __, 119 S. Ct. at 311-312, 48 USPQ2d at 1646-47 (rejecting the "totality of the circumstances" test for determining whether an invention was on sale before the critical date). An invention may be shown to be "ready for patenting," *inter alia*, by "proof of reduction to practice before the critical date." *Id.*

The invention at issue in this case clearly meets the *Pfaff* test. Even though the parties did not know it at the time, it is undisputed that Form IV was the subject matter of at least three commercial sales in the United States before the critical date. It is also clear that the invention was "ready for patenting" because at least two foreign manufacturers had already reduced it to practice. *See Pfaff*, __ U.S. at __ n.2, 119 S. Ct. at 307 n.2, 48 USPQ2d at 1642 n.2 (" 'A composition of matter is reduced to practice when it is completely composed.' ") (*citing Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 383 (1928)). Furthermore, the statutory on-sale bar is not subject to exceptions for sales

4. __ U.S. __, 119 S. Ct. 304, 48 USPQ2d 1641 (1998).

made by third parties either innocently or fraudulently. *See Evans Cooling Sys., Inc. v. General Motors Corp.*, 125 F.3d 1448, 1453-54, 44 USPQ3d 1037, 1040-42 (Fed. Cir. 1997). The fact that these sales were not made by Abbott is therefore irrelevant.

Abbott insists that there can be no on-sale bar unless conception of the invention has been proved, and that the lack of knowledge of the exact crystalline nature of the material that was sold precludes there having been a conception. We disagree that proof of conception was required. The fact that the claimed material was sold under circumstances in which no question existed that it was useful means that it was reduced to practice. In any event, this is not a priority dispute in which conception is a critical issue. The sale of the material in question obviates any need for inquiry into conception.

Abbott cites cases holding that the accidental, unintended, and unappreciated production of the product or process in question does not constitute anticipation. *See, e.g., Tilghman v. Proctor*, 102 U.S. 707, 711-12 (1881) (an accidental and incidental production of fatty acids by means not understood or appreciated did not anticipate a patented process for separating fatty bodies into fatty acids and glycerin); *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). Those cases are all off the point because they involved the issue whether the claimed inventions were anticipated by earlier work that produced no useful or appreciated result. In contrast, the material here, having been sold, was decidedly useful and appreciated.

Abbott argues that the invention was not on sale because those who sold the claimed product did not know all of its characteristics. We disagree. It is well settled in the law that there is no requirement that a sales offer specifically identify all the characteristics of an invention offered for sale or that the parties recognize the significance of all of these characteristics at the time of the offer. *See Scaltech Inc. v. Retec/Tetra, L.L.C.*, Nos. 97-1365, -1480, slip op. at 9 (Fed. Cir. June 4, 1999). If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics. *See id.*; *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1582-83, 229 USPQ 435, 439 (Fed. Cir. 1986) ("[T]he question is not whether the sale, even a third party sale, 'discloses' the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention.") (emphasis in original). In this case, it is undisputed that Form IV falls within the scope of claim 4. The fact that the parties to the sales transactions did not know they were dealing in Form IV at the time of the sales is therefore irrelevant to the question whether it was "on sale" before the critical date.

One of the primary purposes of the on-sale bar is to prohibit the withdrawal of inventions that have been placed into the public domain through commercialization. *See, e.g.*, *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860, 226 USPQ 402, 406 (Fed. Cir. 1985). In this case, significant quantities of Form IV terazosin anhydrate were publicly sold in the United States in 1989-90 and in 1991 and were thus in the public domain when Abbott filed its application in

October 1994. If Abbott's position were adopted, a person could buy or sell a compound whose exact nature had not been determined and then, years after those sales, file a patent application claiming the compound by characteristics newly discovered. The on-sale bar does not permit such a withdrawal of subject matter already available to the public. *Cf. In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (the discovery of a new property of an old compound does not make claims to that compound patentable). For these reasons, we affirm the district court's judgment holding claim 4 of the '207 patent invalid.

CONCLUSION

Because the district court properly granted summary judgment that claim 4 of the '207 patent is invalid under 35 U.S.C. § 102(b), we

AFFIRM.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED AUGUST 28, 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 96 C 3331
Judge Gottschall

ABBOTT LABORATORIES,

Plaintiff,

v.

GENEVA PHARMACEUTICALS, INC.,

Defendant.

No. 96 C 5868
Judge Gottschall

ABBOTT LABORATORIES,

Plaintiff,

v.

NOVOPHARM LIMITED

Defendant.

Appendix B

No. 97 C 7587
Judge Gottschall

ABBOTT LABORATORIES,

Plaintiff,

v.

INVAMED, INC.

Defendant.

MEMORANDUM OPINION AND ORDER

Plaintiff Abbott Laboratories ("Abbott") filed these actions for patent infringement against defendants Geneva Pharmaceuticals, Inc. ("Geneva"), Novopharm Limited ("Novopharm"), and Invamed, Inc. ("Invamed"). Defendants have moved for summary judgment, arguing that the relevant claim of Abbott's patent is invalid under the "on sale" bar of 35 U.S.C. § 102(b). For the reasons set forth below, the motions are granted.

BACKGROUND

Terazosin hydrochloride is a drug for the treatment of hypertension and benign prostatic hyperplasia. It has been marketed exclusively by Abbott under the trademark HYTRIN since about 1987. Abbott's HYTRIN tablets contain terazosin hydrochloride dihydrate, which means that the crystalline arrangement contains two water molecules

for every terazosin molecule. Terazosin hydrochloride also exists in anhydrous crystalline forms.

Abbott's U.S.Patent No. 5,504,207 ("the '207 patent") contains four claims. The first three claims are directed to a process for making hydrated terazosin hydrochloride. Abbott contends that defendants infringed claim 4 of the '207 patent.

Claim 4 of the '207 patent claims a particular anhydrous crystalline form of terazosin hydrochloride, designated by Abbot as "Form IV." Claim 4 defines this Form IV terazosin hydrochloride by reference to the product's x-ray powder diffraction pattern.[1] Claim 4 of the '207 patent characterizes Form IV terazosin hydrochloride by listing the peak positions of several of the peaks in the x-ray powder diffraction powder. (*See* Geneva's Mem., Ex. 1 (Tarling Decl.) ¶ 6.) To be within the scope of claim 4 of the '207 patent, a product must be anhydrous terazosin hydrochloride and must exhibit a powder x-ray diffraction pattern having each of the principal peaks identified in claim 4. (Id. ¶ 7.)

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1. X-ray powder diffractometry is an analytical method used to identify crystalline chemical materials. In this method, a beam of x-rays is directed toward a sample of the material to be analyzed. When the beam strikes the sample, the x-rays are diffracted, or redirected, at various angles. The result is generally depicted on a piece of paper as a series of peaks. The position of the peak reflects the angle at which the x-rays for that peak were diffracted, and the size of the peak is related to the amount of radiation that was scattered at that angle. The x-ray powder diffraction pattern of a crystalline sample is analogous to a fingerprint of the material. The analyst can compare the fingerprint of the sample to that a of a known material and determine whether the two materials are the same or different. (*See* Geneva's Mem., Ex. 1 (Tarling Decl.) ¶ 4.)

Appendix B

Each of the defendants is taking steps to market generic versions of terazosin hydrochloride equivalent to Abbott's HYTRIN. However, unlike Abbott's HYTRIN tablets, which contain terazosin hydrochloride dihydrate, the defendants are planning to market anhydrous terazosin hydrochloride.[2]

In 1984, the Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act to establish an abbreviated process for approval of generic copies of previously approved "pioneer" drug products.[3] The Hatch-Waxman Act allowed the Food and Drug Administration to approve bioequivalent or generic drugs through abbreviated new drug applications ("ANDAs") that rely principally on the safety and effectiveness data developed and submitted by pioneer drug companies.

The Hatch-Waxman Act also amended the patent statutes so that a generic drug manufacturer could perform some research and development without infringing the patents of

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2. Abbott holds a variety of patents for various forms of terazosin hydrochloride. It appears that Abbott held basic patents that effectively covered all forms of terazosin hydrochloride, but these patents expired in 1995. (*See* Geneva's Mem. at 5-6.) Abbott also holds a narrower patent, U.S.Patent No. 5,251,532 ("the '532 patent") covering terazosin hydrochloride dihydrate. This patent expires in the year 2000. The defendants are trying to market anhydrous forms of terazosin hydrochloride rather than the dihydrate form which is still protected by the '532 patent.

3. A "pioneer" drug is the first drug product containing a particular active ingredient that is approved by the FDA for a specified pharmaceutical use. The patent-holding inventor is the pioneer drug company.

the pioneer drug company. *See* 35 U.S.C. § 271(e)(1). However, while generic drug manufacturers are permitted to engage in some research and development activities, it is an act of infringement to submit an ANDA for a drug claimed in a patent 35 U.S.C. § 271(e)(2)(A).

In 1996 defendants Geneva and Novopharm each filed ANDAs for approval to market a generic version of Abbott's HYTRIN product. Defendant Invamed filed a similar ANDA in 1997.

Abbott filed separate actions for infringement of the '207 patent against each of the defendants. The actions were consolidated in this court as related cases under Local Rule 2.31. Defendants Geneva and Novopharm each filed a motion for summary judgment based on the "on sale" bar of 35 U.S.C. § 102(b). Defendants argue that the claim in the '207 patent that was allegedly infringed is invalid because Form IV terazosin hydrochloride was "on sale" in the United States more than one year before the filing date of the application for the '207 patent. Geneva and Novopharm have joined each other's motions for summary judgment and Invamed has joined Geneva's and Novopharm's motions. Therefore, the remainder of this opinion will refer generally to defendants' motions for summary judgment unless otherwise specified.

LEGAL STANDARD

Summary judgment shall be granted if the record shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The '207 patent is presumed valid.

See 35 U.S.C. § 282. To overcome the presumption of validity, the alleged infringer must prove invalidity by clear and convincing evidence. *See In re Mahurkar Hemodialysis Catheter*, 71 F.3d 1573, 1576 (7th Cir. 1995). This higher standard of proof is applicable in a motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

DISCUSSION

The only issue presented in these motions for summary judgment is whether the "on sale" bar of 35 U.S.C. § 102(b) invalidates claim 4 of the '207 patent, requiring dismissal of these actions.

Section 102(b) provides

> A person shall be entitled to a patent unless —
>
> * * *
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale in this country, more than one year prior to the date of the application for patent in the United States* . . . .

35 U.S.C. § 102(b) (emphasis added).

Thus, § 102(b) prohibits an inventor from obtaining a patent on an invention that was "on sale" in the United States

more than one year before the filing date of the inventor's patent application. To use § 102(b) to defend against an infringement action, "the accused infringer must prove by clear and convincing evidence that there was a definite sale or offer to sell more than one year before the application for the subject patent, and that the subject matter of the sale or offer to sell fully anticipated the claimed invention." *Mahurkar*, 71 F.3d at 1576 (quotation omitted). A sale or offer for sale need not be made by the inventor or patent holder. A sale or offer for sale by a third party may also trigger application of the on sale bar. *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1581 (Fed. Cir. 1986); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985).

The application for the '207 patent was filed on October 18, 1994. Therefore the critical date for the on sale bar is October 18, 1993. Defendants claim that they have identified numerous sales of Form IV terazosin hydrochloride prior to October 18, 1993.

1. Sales Prior to October 18, 1993

In December 1989, Geneva placed an order for five kilograms of anhydrous terazosin hydrochloride with Byron Chemical Company, Inc. ("Byron") of New York.[4] Geneva received the anhydrous terazosin hydrochloride on July 10,

4. Byron serves as the intermediary between foreign manufacturers of bulk chemicals and domestic drug manufacturers. The Form IV terazosin hydrochloride allegedly sold before October 18, 1993 was manufactured by foreign companies and shipped to Byron. Byron sold and shipped the terazosin to the domestic drug manufacturers.

1990. Geneva assigned the terazosin hydrochloride a control number, RM 30730.

In August 1991, Geneva ordered another lot of terazosin hydrochloride from Byron. Geneva received the lot of terazosin hydrochloride on December 12, 1991. This lot of terazosin hydrochloride was designated by Geneva as RM 33797.

In 1996, Geneva's expert in x-ray crystallography, Dr. Stephen Tarling, analyzed RM 30730 and RM 33797 by powder x-ray diffractometry.[5] After reviewing the x-ray powder diffraction patterns for RM 30730 and RM 33797, Dr. Tarling found that the patterns for both contained all of the "principal peaks" of claim 4 of the '207 patent. He concluded that the material in the lots designated RM 30730 and RM 33797 is within the scope of claim 4 of the '207 patent, i.e., that it is Form IV terazosin hydrochloride. Dr. Tarling found that RM 30730 was pure Form IV terazosin hydrochloride and that RM 33797 was a mixture of Form IV and Form II terazosin hydrochloride. Geneva also analyzed a sample of RM 33797 in 1993, and the test results indicated that it contained Form IV terazosin hydrochloride.

In its responses to defendants' requests for admission and defendants' 12(m) statements, Abbott admits that RM 30730 and RM 33797 contain Form IV terazosin hydrochloride. (*See* Abbott's Resp. to Geneva's First Set of

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5. It is somewhat unclear from the record when Dr. Tarling performed his analysis. His declaration and the excerpts from his deposition do not indicate when he performed the analysis, but the parties seem to agree that it was done in late 1996 or early 1997.

Requests for Admission, ¶¶ 1-4; Abbott's Resp. to Geneva's 12(m), ¶¶ 15, 16.) Abbott performed its own testing on RM 30730 and RM 33797 in 1995 and found that RM 30730 was Form IV terazosin hydrochloride and that RM 33797 was a mixture of Form IV and Form II.

In October 1990, Byron sold anhydrous terazosin hydrochloride to Warner Chilcott Laboratories ("Warner Chilcott"). In January 1992, Byron sold another batch of anhydrous terazosin hydrochloride to Warner Chilcott. The January 1992 shipment to Warner Chilcott and Geneva's RM 33797 both originated from a lot of terazosin hydrochloride that Byron received from the German drug manufacturer Imhausen-Chemie GMBH. As noted above, Geneva's expert and Abbott both tested RM 33797 and determined that at the time of the testing, RM 33797 contained Form IV terazosin hydrochloride.

Despite these test results, Abbott contends that defendants' have not proved that Geneva's RM 30730 and RM 33797 and the lots sent from Byron to Warner Chilcott contained Form IV terazosin hydrochloride at the time they were sold by Byron. Abbott argues that "it is conceivable that the substances sold by Byron were initially manufactured as a less stable crystal form" of terazosin hydrochloride, and that these "substances converted over time to Form IV" terazosin hydrochloride." (Abbott's Mem. in Opp. at 26.) This seems to be little more than speculation. Abbott has introduced evidence that, in some chemical compounds with multiple crystal forms, one crystal form may convert to a more stable crystal form over time. However, Abbott has introduced no evidence that this type of transformation occurs

with crystal forms of terazosin hydrochloride. Despite Abbott's extensive work with terazosin hydrochloride, Abbott was unable to produce any expert testimony that such a transformation occurs or is likely to occur with terazosin hydrochloride.

The lot of anhydrous terazosin hydrochloride received by Geneva from Byron in 1990 (RM 30730) and the lot of anhydrous terazosin received by Warner Chilcott from Byron in 1990 originated with a Japanese company, Yogodawa Pharmaceutical Company Ltd. (later renamed Sumika Fine Chemical Company Ltd., hereinafter collectively referred to as "Sumika"). The anhydrous terazosin hydrochloride in Geneva's RM 30730 came from Sumika's lot 006T-1. The anhydrous terazosin hydrochloride in Warner Chilcott's 1990 shipment came from Sumika's lot 009T-2. In November 1990, Sumika provided Byron with the results of powder x-ray diffraction analyses for lots 006T-1 and 009T-2. (*See* Novopharm's 12(m), Tab I.)

Abbott does not dispute that these x-ray diffraction analyses indicate the presence of Form IV terazosin hydrochloride.[6] Instead, Abbott claims that these x-ray

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6. In their initial memoranda in support of their motions, defendants made the court's task more difficult by not providing expert testimony that the analyses indicate the presence of Form IV terazosin hydrochloride. While the analyses appear to show the presence of the nine principal peaks that define Form IV terazosin hydrochloride, this court would have been reluctant to reach any conclusions without the assistance of an expert. However, in its motion for leave to file a supplement to its reply, defendant

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diffraction analyses were not properly authenticated. Abbott notes that defendants' have not provided any testimony from anyone at Sumika to authenticate the documents. In response, defendants point out that the analyses were used as an exhibit to the deposition of Byron's 30(b)(6) witness. Defendants cite *First Nat'l Bank Co. of Clinton, Ill. v. Insurance Co. of N. Am.*, 606 F.2d 760, 766 (7th Cir. 1979) for the proposition that on a motion for summary judgment a court may consider exhibits that are made part of a deposition record. However, that case also confirms the general rule that "only evidence or statements that would be admissible at a trial . . . may be considered." *Id.* At the deposition of Byron's 30(b)(6) witness, no foundation was laid to establish the admissibility of the analyses. Defendant Novopharm tried to remedy this shortcoming by attaching a letter from the assistant manager of the research coordination department at Sumika certifying that the analyses are true and correct copies of x-ray pattern diffractions run in October 1990. (*See* Ex. X to Novopharm's motion for leave to file a supplement to its reply.) Setting aside the question whether a summary judgment movant should be able to authenticate documents in a supplement to

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(Cont'd)

Novopharm cited the report of defendants' expert, Dr. Tarling. Dr. Tarling stated in his report that these analyses reveal that the lots contain Form IV terazosin hydrochloride. (*See* Novopharm's Reply, Tab U, ¶ 16.) However, Dr. Tarling did not state this opinion in his declaration (Ex. 2 to Geneva's Mem.), and the defendants did not provide any deposition transcripts containing this opinion. Abbott could have challenged the admissibility of the expert report because it was unsworn. *See Wittmer v. Peters*, 87 F.3d 916, 917 (7th Cir. 1996), *cert. denied*, 117 S. Ct. 949 (1997). Instead, Abbott has challenged the admissibility only of the analyses.

its reply brief, this court finds the letter insufficient to authenticate the documents. The letter does not indicate the assistant manager's responsibilities at Sumika, his knowledge of the tests, whether these documents are kept as business records, or any other basis that would authenticate these documents.

Despite defendants' failure to authenticate test results from 1990, the analyses performed by Dr. Tarling and by Abbott are sufficient to establish that the sales from Byron to Geneva in 1990 and 1992 and from Byron to Warner Chilcott in 1992 were sales of Form IV terazosin hydrochloride. Abbott admits that its own analyses in 1995 and Dr. Tarling's analyses in 1996 demonstrate that, at the time of the tests, the lots contained terazosin hydrochloride. Abbott offers only speculation that the lots might have undergone a transformation between the time of the sale and the time of the tests.[7]

2. Abbott's Arguments Against Application of the On Sale Bar

Though Abbott contends that defendants have failed to prove sales of Form IV terazosin hydrochloride prior to

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7. Because of this finding, the court declines to consider whether Byron's alleged offer to sell terazosin hydrochloride to Zenith Laboratories, Inc. and sales from Sumika to Byron would constitute sales for the on sale bar. As Abbott points out in its objections to Novopharm's motion to supplement its reply, Novopharm failed to indicate until after discovery closed and it had filed its motion for summary judgment that it would rely on the transactions between Sumika and Byron as sales for the purposes of the on sale bar.

Appendix B

October 18, 1993, Abbott spends most of its memorandum in opposition arguing why the sales should not trigger the application of the on sale bar.

Abbott notes that courts have resisted mechanical application of the on sale bar. *See Mahurkar,* 71 F.3d at 1577. Instead, courts have looked to the totality of circumstances, considered in view of the underlying policy justifications for the bar, to determine if the bar should be applied in a particular case. *See id.* In *Mahurkar,* the Federal Circuit identified the policies underlying § 102(b):

> (1) discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available;
>
> (2) encouraging the prompt and widespread disclosure of inventions;
>
> (3) allowing an inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and
>
> (4) prohibiting an inventor from commercially exploiting his invention beyond the statutorily prescribed time.

Id. (citing *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990)).

Here, the third and fourth policies are not implicated because the sales at issue were made by a third party and not

by the inventor. The second policy is also not implicated, as it appears that Abbott promptly applied for the patent after it discovered Form IV terazosin hydrochloride.

Thus, the only policy at issue here is discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available. Abbott argues that this policy would not be violated by upholding the validity of patent '207. According to Abbott, there is no policy justification for finding a patent invalid under the on sale bar where the buyers were unaware that they were purchasing the invention in question. Abbott contends that when the buyers have no knowledge that they are purchasing the invention, they are not relying on the availability of the invention.

Abbott points out that here, the buyers were interested in securing *anhydrous* terazosin hydrochloride rather than *dihydrate* terazosin hydrochloride (which, as noted above, is covered by an Abbott patent until the year 2000). The buyers were not requesting a particular crystal form of anhydrous terazosin hydrochloride. Abbott claims that the buyers were unaware that Form IV terazosin hydrochloride was available at all.

Abbott notes that this was the basis for the Patent Examiner's conclusion that the sales from Byron to Geneva did not require application of the on sale bar.[8] In

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8. Abbott informed the Patent Examiner of the transactions between Byron and Geneva. The Patent Examiner was not aware of

(Cont'd)

awarding the '207 patent to Abbott,[9] the Patent Examiner found

> The two transactions from Byron Chemical Co. to Geneva described in the Information Disclosure Statement filed 12/12/95 are not "on sale" bar of the Form IV of claim 4 because neither Byron or Geneva at the time of the transactions knew that Form IV was involved.

(Abbott's Mem. in Opp., Ex. 1.)

This court disagrees. The first policy reason for the on sale bar — discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available — is implicated here. The buyers were

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(Cont'd)
the transactions between Byron and Warner Chilcott, but the Patent Examiner's reasoning for not declining to apply the on sale bar based on the Byron-Geneva transactions would also seem to apply to the Byron-Warner Chilcott transactions.

9. As noted above, because Abbott was awarded patent '207, Abbott benefits from a presumption of validity. Abbott argues that the decision of the Patent Examiner rejecting application of the on sale bar is entitled to substantial deference. However, the question whether the on sale bar applies is a question of law, *UMC Electronics Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987), and the Patent Office's decisions on questions of law are reviewed "without deference to the views of the Agency." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995). Here, there is not a factual dispute — the Patent Examiner appeared to accept that the sales from Byron to Geneva involved Form IV terazosin hydrochloride. The question is whether these sales should trigger the on sale bar.

counting on the continued availability of anhydrous terazosin hydrochloride. They requested anhydrous terazosin hydrochloride from Byron, and they were supplied, in whole or in substantial part, with Form IV terazosin hydrochloride. They were using this product to develop a terazosin hydrochloride product that would not infringe Abbott's patent for dihydrate terazosin hydrochloride (which is found in the HYTRIN product). These buyers were part of the relevant public for this invention. That they were not aware of the particular crystal form of the terazosin hydrochloride is immaterial. The Form IV terazosin hydrochloride met their needs and they were counting on its continuing availability. Federal Circuit precedent supports this conclusion. *See J.A. LaPorte,* 787 F.2d at 1583 ("[O]ur precedent holds that the question is not whether the sale, even a third party sale, 'discloses' the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention."), *cited in In re Epstein,* 32 F.3d 1559, 1568 (Fed. Cir. 1994).

Abbott cites to *Siemens Aktiengesellschaft v. United States,* 26 Cl. Ct. 980 (1992), but the case is distinguishable. In *Siemens,* the alleged infringer argued that it had received an offer to sell the invention from a third party more than one year before the plaintiff's patent application. The court found that this offer to sell was insufficient to trigger the on sale bar because the offer was not sufficiently specific to show that the particular invention was on sale. Here by contrast, the invention — Form IV terazosin hydrochloride — was actually sold on several occasions more than one year before the critical date.[10]

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10. Moreover, the emphasis in *Siemens* on whether the invention had been "disclosed" is rather anomalous because the invention had been designated "secret" by the United States military.

Abbott also raises two other reasons why the on sale bar should not apply. First, Abbott contends that the subject matter of the Byron sales did not fully anticipate the claimed invention. Again, Abbott relies on the buyers' (and Byron's) apparent failure to appreciate that the terazosin hydrochloride involved in the transactions was the crystal form later claimed by Abbott as Form IV. In support of this contention, Abbott cites to several cases that have found that accidental, unappreciated products and processes do not anticipate. *See Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923); *Tilghman v. Proctor*, 102 U.S. 707, 710-11 (1881); *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 498 F. Supp. 28, 35-36 (E.D. Pa. 1980). Here, however, the anhydrous terazosin hydrochloride was not merely an accidental byproduct. Rather, it was the product requested by the buyers and intentionally produced by the seller. The apparent failure of the parties to appreciate that the product had a particular crystal form does not overcome the fact that Form IV terazosin hydrochloride was sold more than one year before Abbott applied for patent '207.

Second, Abbott contends that defendants have not shown that the invention was complete on the dates of the sales. In particular, Abbott argues that defendants have not shown that the sale in question involved "a completed invention" that was "known to work for its intended purpose." *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1324 (Fed. Cir. 1996). However, the evidence shows that the terazosin hydrochloride was acceptable for the buyers' intended uses. The buyers sought to obtain anhydrous terazosin hydrochloride from the seller. Documents relating

to Geneva's purchases indicate that the purpose for Geneva's purpose was "development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." (Geneva's Mem., Ex. 3 (Pelloni Decl.) Ex. A.) Geneva wanted to use the anhydrous terazosin hydrochloride in developing an equivalent to Abbott's HYTRIN product, and the anhydrous terazosin hydrochloride was adequate for this purpose. Abbott's argument that the manufacturers did not have a process for consistently manufacturing Form IV terazosin hydrochloride is unavailing; claim 4 of the '207 patent is for a product not for a process.

CONCLUSION

Defendants' motions for summary judgment are granted. Claim 4 of the '207 patent is invalid because Form IV terazosin hydrochloride was on sale, within the meaning of 35 U.S.C. § 102(b), more than one year before Abbott filed its application for the '207 patent.

ENTER:

s/ Joan B. Gottschall
JOAN B. GOTTSCHALL
United States District Judge

DATED: August 28, 1998

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DATED AND FILED AUGUST 5, 1999

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for rehearing and suggestion for rehearing en banc having been filed by the APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing en banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on August 12, 1999.

Circuit Judge SCHALL did not participate in the vote.

FOR THE COURT,

s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

Dated: August 5, 1999

Appendix C

ABBOTT LABS V GENEVA PHARMACEUTICAL, 98-1593, -1594, -1595
(DCT — 96-CV-3331)

OPPOSITION

BRIEF

No. 99-753

Supreme Court, U.S.
FILED
NOV 30 1999
CLERK

IN THE

Supreme Court of the United States

ABBOTT LABORATORIES,
Petitioner,

—v.—

GENEVA PHARMACEUTICALS, INC., NOVOPHARM, LTD. and INVAMED, INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR GENEVA PHARMACEUTICALS, INC.

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RESPONDENT'S STATEMENT UNDER RULE 29.6

Respondent Geneva Pharmaceuticals, Inc., is a wholly-owned subsidiary of Novartis Finance Corporation, which is a wholly-owned subsidiary of Novartis Corporation, which is a wholly-owned subsidiary of Novartis Holding AG, which is a wholly-owned subsidiary of Novartis AG, which is a publicly-held company.

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INTRODUCTION

A unanimous panel of the Federal Circuit affirmed that claim 4 of Abbott Laboratories' ("Abbott's") '207 patent is invalid because the claimed invention, the chemical compound known as "Form IV" terazosin hydrochloride, was "on sale" in the United States more than one year before Abbott filed its patent application claiming it. *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999). (App. 1a-9a). The panel denied Abbott's motion for rehearing, and the full court declined Abbott's suggestion for rehearing *en banc*. (App. 28a-29a). In holding Abbott's patent claim invalid, the Federal Circuit correctly applied this Court's precedents as well as its own. In addition, the Federal Circuit's decision raises no issues of importance to the public or to industry. Abbott's petition should therefore be denied.

RESPONDENT'S STATEMENT OF THE CASE

The chemical compound terazosin hydrochloride is known to exist in different crystal forms. That is, its molecules can arrange themselves in any one of several different regular patterns in space. The '207 patent claims a specific crystal form of that compound, referred to as "Form IV" terazosin hydrochloride. Whether a sample of terazosin hydrochloride is Form IV or some other form can be determined by analyzing it using a technique called powder x-ray diffractometry. The '207 patent characterizes Form IV by a set of numbers generated by that analysis. (App. 11a-12a).

Years before Abbott had ever made Form IV terazosin hydrochloride, respondent Geneva Pharmaceuticals, Inc. ("Geneva"), a manufacturer and distributor of pharmaceuticals,

decided to develop a drug product that contained terazosin hydrochloride as the active ingredient. As part of that effort, Geneva purchased two lots (a total of ten kilograms[1]) of terazosin hydrochloride from Byron Chemical Co. ("Byron"), a New York-based supplier of bulk pharmaceuticals.[2] Geneva bought one lot in 1990 and another in 1991. In addition, another pharmaceutical company, Warner Chilcott, Inc. ("Warner Chilcott") purchased terazosin hydrochloride from Byron in 1992. (App. 3a). It is undisputed that the product both Geneva and Warner Chilcott purchased was Form IV terazosin hydrochloride. At the times of the sales, however, neither purchaser determined that the product it was buying had that particular crystal form. (App. 3a-4a).

Although none of the parties to the transactions knew that the products had any particular crystal form at the times of the sales, there is no dispute that the buyers received exactly what they ordered. In particular, Geneva tested the materials it received and determined that they met Geneva's specifications and were suitable for Geneva's purposes. Thus, Abbott's "Question Presented" is wrong in presuming that Byron and Geneva "were unaware of [the] existence" of what they were selling and buying. In fact, they were aware of the existence of the product because Geneva specifically ordered, received and paid for it, and Byron filled the order by supplying what Geneva had specifically requested.

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[1] Ten kilograms is enough for several million individual tablet doses of terazosin hydrochloride.

[2] Byron acts as an intermediary, buying bulk drugs from foreign manufacturers and selling them to U.S. manufacturers of pharmaceutical dosage forms. (App. 16a n.4).

About four years after Byron first sold Form IV terazosin hydrochloride to Geneva, Abbott apparently made it for the first time. In October 1994, Abbott filed a patent application claiming Form IV terazosin hydrochloride. That application issued in as the '207 patent in 1996.

Based on these facts, none of which Abbott disputed, the district court granted defendants' motions for summary judgment that claim 4 of the '207 patent was invalid. The court held that the facts were undisputed that all three sales were commercial transactions, and that the product sold in each was Form IV terazosin hydrochloride. The court held that these sales placed the claimed invention of the '207 patent "on sale" as that term is used in 35 U.S.C. § 102(b). On appeal, the Federal Circuit affirmed. Abbott's principal argument, which both courts rejected and which it repeats here, is that because the sellers and customers allegedly did not know the crystal form of the product they were buying and selling, the indisputably commercial transactions did not place the patented invention "on sale" for purposes of section 102(b).

REASONS FOR DENYING THE WRIT

I. THE COURTS BELOW CORRECTLY APPLIED SETTLED PRINCIPLES OF LAW

The relevant statute, 35 U.S.C. § 102(b), prohibits the patenting of subject matter that was "on sale" more than one year before the filing of the application for the patent. The fact that the sales here involved third parties unrelated to the patent owner does not make that prohibition inapplicable. *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1453-54 (Fed. Cir. 1997). (App. 6a-7a). Indeed, Abbott

concedes the applicability of the "on sale" bar to third party sales.

Abbott's argument here boils down to the proposition that it is entitled to a patent on a product that was commercially available in the United States for years before Abbott itself ever made that product merely because Abbott was the first to carry out a particular test on it and write down the results of that test. Abbott's theory, however, is inconsistent with the long-settled principle that a patent cannot be obtained merely for describing or discovering properties that are inherent in old products. This Court's decision in *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 248-49 (1945), is precisely on point. There, the inventor apparently discovered that a product already in the prior art possessed enhanced strength compared to other products in the marketplace. He received a patent on the product based on this discovery of its inherent properties that no one else had yet appreciated. This Court held the patent invalid, stating:

> It is not invention to perceive that the product which others had discovered had qualities they failed to detect.

Thus, the Federal Circuit was correct in holding that it was not invention for Abbott to perceive that the product Byron sold and Geneva and Warner Chilcott purchased had a particular crystal form.

General Electric has in substance been consistently followed by the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals. *See, e.g., In re Spada*, 911 F.2d 705, 706 (Fed. Cir. 1990):

> The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition.

See also Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342 (Fed. Cir. 1999); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436 (Fed. Cir. 1988) (to establish anticipation, defendant not required to prove that prior inventors were aware that their composition possessed property recited in claims of plaintiff's patent); *Verdegaal Brothers, Inc. v. Union Oil Co.*, 814 F.2d 628, 633 (Fed. Cir.), *cert. denied*, 484 U.S. 827 (1987) (existence of property was inherent in prior art device, even though not recognized); and *In re Swinehart*, 439 F.2d 210, 212-213 (C.C.P.A. 1971):

> It is elementary that the mere recitation of a newly discovered property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.

These decisions control here: Form IV terazosin hydrochloride was a product of commerce in the United States years before Abbott ever heard of it. Abbott is not entitled to a patent simply for discovering and cataloging its properties.

II. THE FEDERAL CIRCUIT'S DECISION IS IN ACCORD WITH *PFAFF v. WELLS ELECTRONICS*

In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998), this Court considered the circumstances under which an inventor who has not reduced the patented invention to practice can nevertheless place it "on sale" for purposes of section 102(b). In *Pfaff*, the inventor had made detailed drawings of his invention before offering it for sale, but had not made the device itself. This Court held that the offer placed the invention "on sale" even though the inventor had not yet reduced the invention to practice. The Court established a rule that an inventor places his invention "on sale" if the "product is the subject of a commercial offer for sale," and if the invention is "ready for patenting." 525 U.S. at ___, 119 S. Ct. at 311-12. The Court did not address how the analysis would differ, if at all, in the context of a third party sale.

Notwithstanding that the transactions here, unlike the offer in *Pfaff*, did not involve the inventor, the Federal Circuit treated *Pfaff* as applicable. The Federal Circuit pointed out that the invention, Form IV terazosin hydrochloride, was ready for patenting at the time of the sale because it was fully "reduced to practice," since at least two manufacturers had produced it, and "no question existed that it was useful . . . ." (App. 6a-7a). In so doing, the Federal Circuit relied on *Corona Tire Cord Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 383 (1928), which holds that a composition of matter is "reduced to practice" when it is made.

In attacking the Federal Circuit's reasoning, Abbott relies primarily on an out-of-context paraphrasing of a statement in *Pfaff* that "the primary meaning of the word 'invention' in the Patent Act unquestionably refers to the inventor's conception

rather than to a physical embodiment of that idea." 525 U.S. at ___, 119 S. Ct. at 308. (Pet. at 7). That statement, however, and the other portions of *Pfaff* to which Abbott refers, appears in the context of this Court's holding that an invention may be "on sale" even though the inventor who conceives an invention does not take the next step – a "reduction to practice." That is, because in some instances the mere conception of an invention can be sufficient to support a patent for it, its reduction to practice is not necessarily required before it can be placed "on sale." Nowhere in *Pfaff*, however, did this Court hint that a composition of matter, fully reduced to practice and the subject of repeated commercial transactions, cannot be "on sale" absent proof that the seller or buyer "conceived" of or "appreciated" particular characteristics of that composition. Indeed, such a holding would be inconsistent with *General Electric*, *supra*.

To support its misreading of *Pfaff*, Abbott relies on decisions dealing with patent "interferences," that is, proceedings to determine which of two or more patent applicants was the first to invent common subject matter claimed in their applications. *See* 35 U.S.C. § 135. (Pet. at 11-12). Such a determination, by statute, requires an inquiry into which inventor was the first to conceive the invention. 35 U.S.C. § 102(g)[3]. That determination is irrelevant here: neither

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[3] Section 102(g) states:

> . . . In determining priority of invention, there shall be considered not only the respective dates of conception and reduction to practice, but also the reasonable diligence of one who was the first to conceive and the last to reduce to practice, from a time prior to conception by

Byron (the seller) nor Geneva (the buyer) is seeking a patent, neither is entitled to a patent, and neither claims that it was the first to invent Form IV terazosin hydrochloride. Section 102(b) does not require or even permit an inquiry into who was the first inventor of the claimed invention. (App. 7a). Unlike the interference statutes, section 102(b) prohibits anyone from obtaining a patent on subject matter that was in public use or on sale in the United States more than a year before the application filing date, irrespective of who may have conceived it first.

Abbott's reliance on the "accidental anticipation" doctrine exemplified by *Tilghman v. Proctor*, 102 U.S. 707 (1881), is equally misplaced. Abbott does not dispute that the product that Geneva and Warner Chilcott purchased in "significant quantities" (App. 8a) was produced deliberately, rather than accidentally or unwittingly. The Federal Circuit noted this distinction:

> Those cases are all off the point because they involved the issue whether the claimed inventions were anticipated by earlier work that produced no useful or appreciated result. In contrast, the material here, having been sold, was decidedly useful and appreciated.

(App. 7a).

Finally, Abbott's reading of *Pfaff* would frustrate a principal purpose of the "on sale" bar: to prevent withdrawal from the marketplace of products that have become legitimately available to the public through commercialization. As the

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the other.

Federal Circuit stated:

> If Abbott's position were adopted, a person could buy or sell a compound whose exact nature had not been determined and then, years after those sales, file a patent application claiming the compound by characteristics newly discovered. The on sale bar does not permit such withdrawal of subject matter already available to the public.

(App. 8a-9a).

III. THE FEDERAL CIRCUIT'S DECISION DOES NOT RAISE ANY ISSUE OF IMPORTANCE TO THE PUBLIC OR TO INDUSTRY

Abbott's petition raises no issues that have not been thoroughly reviewed and consistently resolved by this Court and lower courts. Abbott presents no justification for revisiting those issues now. This Court and the Federal Circuit have consistently and correctly rejected Abbott's theory that a valid patent can be issued for merely discovering the inherent properties of an old product. The law in this area is well developed, readily applied, and conforms to the statute and the public policies it is designed to express.

CONCLUSION

For the foregoing reasons, Abbott's petition for a writ of certiorari should be denied.

Respectfully submitted,

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